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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 305

[Docket No. APHIS-2013-0081]

RIN 0579-AD90

Standardizing Phytosanitary Treatment Regulations: Approval of Cold Treatment and Irradiation Facilities; Cold Treatment Schedules; Establishment of Fumigation and Cold Treatment Compliance Agreements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the phytosanitary treatment regulations to establish generic criteria that would allow for the approval of new cold treatment facilities in the Southern and Western States of the United States. These criteria, if met, will allow us to approve new cold treatment facilities without rulemaking and facilitate the importation of fruit requiring cold treatment while continuing to provide protection against the introduction of pests of concern into the United States. We are also amending the fruit cutting and inspection requirements in the cold treatment regulations in order to expand cutting and inspection to commodities that have been treated for a wider variety of pests of concern. This action will provide for a greater degree of phytosanitary protection. We are also adding requirements concerning the establishment of compliance agreements for U.S. entities that operate fumigation facilities. Finally, we are harmonizing language concerning State compliance with facility establishment and parameters

for the movement of consignments from the port of entry or points of origin in the United States to the treatment facility in the irradiation treatment regulations with language in the cold treatment regulations. These actions will serve to codify and make enforceable existing procedures concerning compliance agreements for these facilities.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. David B. Lamb, Senior Regulatory Policy Specialist, IRM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2103.

#### SUPPLEMENTARY INFORMATION:

##### Background

The phytosanitary treatments regulations in 7 CFR part 305 set out general requirements for certifying or approving treatment facilities and for performing treatments listed in the Plant Protection and Quarantine (PPQ) Treatment Manual<sup>1</sup> for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. Within part 305, § 305.6 (referred to below as the regulations) sets out requirements for treatment procedures, monitoring, facilities, and enclosures needed for performing sustained refrigeration (cold treatment) sufficient to kill certain insect pests associated with imported fruits and vegetables and with regulated articles moved interstate from quarantined areas within the United States. Under the regulations, all facilities used to provide upon arrival cold treatment for these articles must operate under a compliance agreement with the Animal and Plant Health Inspection Service (APHIS) and be certified as capable of delivering required cold treatment and handling articles to prevent reinfestation of treated

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<sup>1</sup> The PPQ Treatment Manual is available at [http://www.aphis.usda.gov/import\\_export/plants/manuals/ports/downloads/treatment.pdf](http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf).

articles. An inspector<sup>2</sup> monitors all upon arrival treatments. The regulations require safeguards to prevent the escape of pests during transportation to and while at the facility. These include, but are not limited to, inspections, precooling, and physical separation of untreated and treated articles. The facility must maintain records of all treatments and must periodically be recertified. These conditions have allowed for the safe, effective treatment of many different kinds of articles, as is demonstrated by the track record of cold treatment facilities currently operating in the United States and other countries.

#### Cold Treatment in Southern and Western States

In § 305.6, paragraph (b) allows cold treatment facilities to be located in the area north of 39° latitude and east of 104° longitude. When the cold treatment regulations were established, areas outside of these coordinates were identified as having conditions favorable for the establishment of exotic fruit flies. The location restrictions served as an additional safeguard against the possibility that fruit flies could escape from imported articles prior to treatment and become established in the United States.

Although the regulations initially did not allow cold treatment facilities to be located in Southern and Western States, APHIS periodically received requests for exemptions. In response to these requests, APHIS conducted site-specific evaluations for these locations and determined that regulated articles can be safely transported to, handled in, and treated by specific cold treatment facilities outside of the areas established by the regulations under special conditions to mitigate the possible escape of pests of concern. Over the years, APHIS has amended its regulations to allow cold treatment facilities to be located at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport,

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<sup>2</sup> Section 305.1 defines an *inspector* as “Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.”

Seattle, WA; Hartsfield-Atlanta International Airport, Atlanta, GA; and, most recently, MidAmerica St. Louis Airport, Mascoutah, IL.

In addition to those requests, certain importers of fruits and vegetables have shown considerable interest in locating cold treatment facilities in places that are not currently allowed under the regulations (e.g., Miami and Port Everglades, FL, and Savannah, GA).

On June 30, 2016, we published in the *Federal Register* (81 FR 42569 - 42576, Docket No. APHIS-2013-0081) a proposal<sup>3</sup> to amend the regulations by establishing generic phytosanitary criteria that would replace the current location-specific criteria for cold treatment facilities at the ports mentioned previously and would also apply to the approval and operation of new cold treatment facilities in the Southern and Western States of the United States.

We also proposed to expand our requirements for initial cold treatment facility certification and recertification; expand the fruit cutting and inspection requirements in order to state that consignments treated for other fruit flies and pests of concern may be subject to sampling and cutting; combine requirements both domestic and foreign cold treatment facilities and importers would have to meet in order to enter into a compliance agreement with APHIS; add language regarding compliance agreements required in association with articles moved interstate from Hawaii and the U.S. territories; add a section to the regulations concerning fumigation treatment to provide that both domestic and foreign fumigation treatment facilities and importers enter into a compliance agreement with APHIS; add a definition for “treatment facility” to the regulations in § 305.1; and remove a cold treatment schedule from the PPQ Treatment Manual.

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<sup>3</sup> To view the proposed rule, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0081>.

We solicited comments concerning our proposal for 60 days ending August 29, 2016. We received 42 comments by that date. They were from producers, exporters, industry groups, private citizens, and a State department of agriculture. Of those, 26 were wholly supportive of the proposed action. The remainder are discussed below by topic.

#### General Comments

Several commenters argued that granting the exemptions described previously that have allowed for the establishment of cold treatment facilities in a number of Southern and Western States mistakenly served to further liberalize the regulations and lessen the phytosanitary safety of the United States.

As stated previously, prior to the establishment of those cold treatment facilities, we conducted site-specific evaluations for each location and determined that regulated articles could be safely transported to, handled in, and treated subject to special conditions designed to mitigate the possible escape of pests of concern. These evaluations and proposals were made available both to the States in which the facilities would be established and the general public for review and comment. We have successfully established cold treatment facilities in seven locations outside of the areas established by the regulations and they have operated without incident. If a facility were to be found out of compliance with the requirements of the regulations, we would take appropriate remedial action to ensure ongoing phytosanitary security.

A number of commenters hypothesized that the proposed rule was intended to satisfy nonagricultural entities (e.g., importers, facility owners) with little concern for the phytosanitary risk involved to the agricultural sector.

We have determined that the measures specified in the treatment evaluation document (TED) that accompanied the proposed rule (e.g., requirements concerning facility planning and

location, transport of regulated articles to the facility for treatment, and handling of regulated articles after treatment) will effectively lessen the risk associated with locating cold treatment facilities in the Southern and Western States of the United States. In addition, as noted in the proposed rule, the criteria we are establishing are similar to those successfully used for the approval of new irradiation facilities in the Southern United States found in § 305.9 of the regulations, as untreated fruit moving to irradiation facilities in those States presents the same pest risks as untreated fruit moving to cold treatment facilities. APHIS' evaluation process is solely based on this evaluated level of phytosanitary risk and not on the identity of any of the individuals or entities supportive of the change. The commenters did not provide any evidence suggesting that the measures are not effective.

One commenter asked about the impetus for the proposed rule. The commenter suggested that greater flexibility for importers and a higher volume of imports serving as a revenue generating device for ports were the two obvious motivations for the change.

We developed the proposed rule in response to a number of pending requests for the approval of cold treatment facilities. After considering the issue and the associated phytosanitary risks, we determined that generic criteria could be established for the approval of new facilities that would streamline the approval process while at the same time minimizing the risk of pests escaping from regulated articles prior to cold treatment.

Another commenter stated that U.S. Customs and Border Protection (CBP) has reported pest interceptions and that the volume of those interceptions is greater today than it was in the past.

The commenter provided no evidence to support the claim of increased pest interceptions related to commercial commodities imported or moved interstate in the United States for cold

treatment. In addition, the commenter did not specify the identities of the pests of concern, the commodities with which the pests are associated, whether those commodities were imported or moved commercially or non-commercially, or what State or States are the focus of particular concern when it comes to the supposed increase in interceptions. In the absence of specific information we cannot provide targeted CBP data to address the commenter's claim, however we have not noted a general increase in pest interceptions.

#### Comments on Phytosanitary Security

One commenter expressed concern over the phytosanitary risk inherent in allowing untreated fruits and vegetables to travel through areas where host material may exist to a facility in proximity to domestic host material. Another commenter said that APHIS should not allow cold treatment facilities to be located near areas producing domestic host material, nor should we allow access to such facilities via highways or railways that run through areas producing host material. One commenter stated that invasive species are not introduced directly to farming communities, but instead become established first in urban areas adjacent to ports or terminal markets before spreading elsewhere. The commenter urged us to examine this phenomenon.

A number of commenters expressed specific concerns regarding potential pest incursion into the State of Florida. One commenter stated the recent establishment of citrus canker, citrus black spot, and citrus greening should serve to eliminate Florida as a potential location for cold treatment facilities. Four commenters said that, due to the overall risk of fruit fly and other pest introduction to the State of Florida, APHIS should exclude commodities originating from areas where certain fruit flies are known to exist from the consolidated regulations. Two commenters said that cold treatment should be completed prior to any shipment's arrival in the State of Florida in order to ensure the phytosanitary security of domestic crops. Another commenter

argued that because foreign production areas are not well monitored, cold treatment should occur prior to departure from the shipment's country of origin.

The regulations in § 305.6 allow for cold treatment of articles either prior to or after arrival in the United States, provided that an APHIS-approved facility is available. Articles may be treated in the United States instead of the exporting country for several reasons, including when the exporting country lacks the resources, technical expertise, or infrastructure to treat articles prior to export. The regulations require safeguards that have successfully prevented the introduction or dissemination of plant pests into or within the United States via the importation or interstate movement of cold treated articles in the past. Based on our experience, we are confident that exporting countries have the ability to comply with all APHIS requirements and commodities from exporting countries can be safely treated in the United States.

APHIS recognizes that the Southern and Western States of the United States have conditions favorable for the establishment of certain pests, and that is why we proposed additional safeguards for cold treatment facilities in these States that go beyond the current requirements that apply to all cold treatment facilities. These safeguards include the requirements that untreated articles may not be removed from their packaging prior to treatment under any circumstances, that refrigerated or air-conditioned conveyances must be used to transport regulated articles to the treatment facility, and that facilities have contingency plans for safely destroying or disposing of regulated articles if the facility was unable to properly treat a shipment. To help prevent establishment of pests in the unlikely event that they escape despite the required precautions, we will require trapping and other pest monitoring activities within 4 square miles of the facility to help prevent establishment of any escaped pests of concern. Those activities will be paid for by the facility.



APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from a port of entry or points of origin in the United States. We believe that the mitigations included in this final rule have proven effective in mitigating the risk associated with the importation of commodities into the United States, and thus will provide protection against the introduction or dissemination of pests of concern into the United States.

A number of commenters asked what had changed in APHIS' assessment of phytosanitary risk since the cold treatment regulations were originally established. The commenters specifically pointed to § 305.6(b), which states that "cold treatment facilities are to be located in the area North of the 39th latitude and east of the 104th longitude as areas outside of these coordinates are identified as having conditions favorable for the establishment of exotic fruit flies." The commenters argued that the original justification for the prohibition on facility location is still valid.

The TED that accompanied the proposed rule referenced a study conducted in 1994, which was the basis for our initial decision to prohibit the movement of host materials to cold treatment facilities in the Southern and Western States of the United States. The study recommended restricting or prohibiting the movement of host materials through these States unless strict measures were applied to manage the associated risks. Since that time, in response to petitions and after site-specific evaluations, APHIS has approved several Southern and Western locations where facilities could be established to receive and cold treat foreign fruits or vegetables provided certain conditions determined by APHIS to result in the safe transport of regulated articles to the treatment facility, were followed. It is our experience with these

stringent, additional measures that has led us to conclude that generic criteria can be safely established.

Many commenters stated that the potential escape of fruit flies represented too great a phytosanitary risk and added that the proposed regulations could expose domestic citrus crops to citrus leprosis virus, spread by *Brevipalpus* mites. Several other commenters cited the dangers to the domestic avocado industry posed by laurel wilt, spread by the ambrosia beetle (*Xyleborus glabratus*). Another commenter argued that even with restrictions in place, devastating insects such as the emerald ash borer (*Agrilus planipennis*, EAB), Asian longhorned beetle (*Anoplophora glabripennis*, ALB), and brown marmorated stink bug (*Halyomorpha halys*) eluded detection, established, and spread. One commenter used the State of Florida's Mediterranean fruit fly (*Ceratitis capitata*, Medfly) trapping program as a cautionary example. The commenter stated that, despite the State's use of trapping and the release of sterile insects, accidental incursions of Medfly occurred in 2010 and 2011, resulting in a cost of approximately \$4 million in each case to achieve eradication.

As this rule does not certify any additional cold treatment facilities, such specific pest concerns are outside the scope of the current regulation, although we note that the introductions of EAB, ALB, and brown marmorated stink bug were all associated with wood packing material, which, at the time of the pests' first entrance into the United States, was not safeguarded at the level of imported fruits and vegetables. Any new treatment facilities would have to be authorized using the criteria described in the regulation, which would include analysis of any potential host materials in the area. The commenter did not specify whether the Medfly incursions in 2010 and 2011 were determined by the State of Florida to originate from commercial or noncommercial sources, but we would note that accidental incursions of fruit flies

from commercially produced fruit represent less phytosanitary risk, as produce grown commercially is less likely to be infested with plant pests than noncommercial consignments due to the standardized way in which it is grown, harvested, and packaged.

A commenter said that the cumulative results of authorizing cold treatment facilities in the Southern and Western States of the United States should not be ignored. The commenter argued that, while individual approvals may create negligible risk, taken as a whole they lead to an overall decline in phytosanitary safety. The commenter further stated that the subsequent establishment of quarantine pests domestically then hampers the ability of domestic producers to export their products due to increased stringency in import markets abroad.

We disagree with the commenter's point. While it is true that cold treatment facilities were and will continue to be evaluated on an individual basis, as stated previously, the fact that pests of concern are more likely to become established in the Southern and Western States of the United States is why we proposed additional safeguards for cold treatment facilities in these States that go beyond the current requirements that apply to all cold treatment facilities. We disagree that any increase in the number of authorized cold treatment facilities will necessarily create an unacceptable level of risk. Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. Location information would include any nearby facilities and those facilities would be a part of APHIS' overall consideration of plant health risks for the requested location. We also note that the requirements regarding safeguarding during transit to, treatment, and shipment from the facilities will also serve to preclude escape of quarantine pests into the environment, regardless of the number of other treatment facilities in a given area. The commenter provided no evidence that the establishment of quarantine pests in

domestic host material is a given, therefore the commenter's final point about potential impacts to domestic producers does not apply.

#### Comments on Implementation

Two commenters expressed concern at the elimination of the need for rulemaking for future individual cold treatment facility approvals in Southern and Western States. The commenters were particularly worried about the elimination of a public comment period and other stakeholder outreach methods.

Prior to approving a new cold treatment facility, APHIS will enter into consultation with the State in which the prospective facility will be located. Facility approval will be coordinated through APHIS' Field Operations unit, which routinely keeps potentially affected stakeholders apprised of any pending APHIS approvals. These actions will serve to complement the State's own outreach. As circumstances warrant APHIS may use additional outreach tools.

One commenter was partially supportive of our proposal but suggested that we require that approved cold treatment facilities also be approved to apply alternative treatments, such as fumigation with methyl bromide or irradiation.

While it is certainly possible for a treatment facility to be certified to perform more than one variety of treatment, we see no reason to require that cold treatment facilities be so certified because we are confident that our regulations require that any regulated articles be separated prior to, during, and after treatment. If a facility were to engage in different varieties of treatment those treatments would be required to be completed separate from one another.

Another commenter recommended that we require, whenever possible, that phytosanitary treatments be performed prior to shipment arrival in the United States in order to prevent accidental introduction of pests of concern.

As stated previously, the regulations in § 305.6 allow for cold treatment of articles either prior to or after arrival in the United States, provided that an APHIS-approved facility is available.

The State government of the Southern or Western State in which the facility will be located will also have to concur in writing with the location of the cold treatment facility. If the State government does not concur, it must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, then APHIS and the State will need to agree on a strategy to resolve such risks before APHIS approves the facility.

A commenter suggested that we stipulate that written explanations be provided within 60 days of the submission of the required documents by the prospective facility owner. The commenter also suggested that, in instances where the State government does not concur with the proposed facility location, APHIS and the State will agree on a strategy to resolve the pest risk concerns prior to APHIS approval within a reasonable period not to exceed 120 days from the submission of the required documents by the prospective facility owner.

A reasonable length of time to be determined by APHIS will be given for the State to respond after the proposal for the location and layout of the facility site are submitted to APHIS by the prospective facility owner. Time frames for response will be determined on a case-by-case basis, based on APHIS' own evaluation of the submitted materials.

One commenter asked that a State's ability to maintain an objection to the placement of a cold treatment facility beyond the stipulated consultation and negotiation with APHIS be specifically addressed in the regulations.

As stated previously, we will first come to concurrence with the State in which the prospective cold treatment facility will be located before approving the facility. Because concurrence is reached on a case-by-case basis, this allows us to ensure that the State's phytosanitary risk-based concerns have been thoroughly addressed.

Another commenter said that a State should not be able to veto a given proposal simply because it opposes the establishment of cold treatment facilities within its borders or insists upon an unrealistic level of phytosanitary protection. The commenter requested language be included that assures prospective facility owners that reasonable efforts will be made to come to agreement on the establishment of facilities deemed acceptable by APHIS and objectionable by individual States.

The standards are similar to the procedure we successfully use for the approval of irradiation facilities in Southern and Western States as currently described in § 305.9. In instances where the State government does not concur with the proposed facility location, APHIS and the State will collaborate to resolve these concerns. These requirements are intended to give States an opportunity to provide information to APHIS to help ensure that all facilities will have appropriate safeguards in place prior to APHIS approval.

Several commenters argued that cold treatment facilities should not be located in the State of Florida due to its wide range of diverse habitats and climate ranges and the resulting likelihood of accidental exotic plant pest introduction and establishment.

While APHIS acknowledges that Florida's environment is uniquely hospitable to the establishment of certain plant pests, the generic criteria for establishing cold treatment facilities in Southern and Western States include safeguarding measures above and beyond those already in place for facilities located elsewhere in the country. Additionally, when the location of the

proposed facility raises phytosanitary concerns that are not addressed by the generic criteria, additional safeguards will be required for any facility established in that area, such as increased inspections and trapping based on quarantine pests associated with specific regulated articles. Any additional measures mandated for a particular facility will be stipulated in the facility compliance agreement. Finally, States will have the opportunity to review the layout of the facility and its proposed location prior to any APHIS approval, and to present pest risk concerns that may be associated with the facility or its location that necessitate further safeguarding. It is possible that, collectively, these safeguards would mitigate phytosanitary risk to a level allowing for the establishment of a facility in the State of Florida. We therefore cannot grant the commenter's request for a blanket prohibition on constructing facilities in that State.

#### Comments on General Economic Effects

While specific comments on the initial regulatory flexibility analysis are specifically addressed in this document and in the final regulatory flexibility analysis, we received a number of comments concerning the overall economic effect of the rule as it relates to the establishment of generic criteria that would allow for the approval of new cold treatment facilities in the Southern and Western States of the United States.

One commenter cited the World Trade Organization's (WTO) Article 5, "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection," which states: "In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-

effectiveness of alternative approaches to limiting risks.” The commenter argued that the establishment of generic standards that eliminate the need for rulemaking to approve new facilities, and thus the elimination of the economic analyses that would be prepared as part of the rulemaking process, is in conflict with the WTO mandate, as it will impact APHIS’ ability to consider such consequences. The commenter concluded that it is not reasonable for APHIS to make a blanket determination that the future economic impact of unspecified foreign imports entering the United States for cold treatment will always be of little significance.

We disagree that our actions are in conflict with WTO Article 5. While specific economic analyses will not be conducted in connection with approvals of new cold treatment facilities, the potential economic consequences of pest introduction associated with a given commodity are considered at the same time we consider potential mitigation measures during the development of the risk mitigation document that accompanies proposed actions.

Several commenters stated that the financial consequences of pest infestation would be too great to allow for any imported host material to be treated in the Southern or Western States.

We believe that the cold treatment and the additional specific safeguarding measures that will be in place at a given facility under compliance agreement are adequate to mitigate the phytosanitary risks presented by such materials. If the risks cannot be adequately mitigated, a facility or specific commodities would not be approved.

#### Comments on the Economic Analysis

One commenter observed that, while it is true that the rule does not approve individual facilities, it creates the mechanism for all future approvals. The commenter argued that we should therefore project the economic impact of utilization of the new process at various levels of intensity over time.



The commenter is correct that the economic impact of any new facilities is not a direct result of this rulemaking. However, we do recognize that facilities that are currently awaiting approval will reasonably be expected to be evaluated under the new criteria of this rule. We have included a discussion of these facilities in the analysis for the final rule.

The same commenter said that the economic analysis failed to consider the full scope of small entities potentially affected by the rule. The commenter stated that we should include possible impacts on farming activities in Southern and Western States that could be impacted by phytosanitary threats that are intended to be mitigated by cold treatment.

We disagree. As stated previously, we believe that the additional specific safeguarding measures that will be required at a given facility under compliance agreement in a Southern or Western State will adequately mitigate the phytosanitary threats presented. If threats cannot be adequately mitigated, a facility or specific commodities will not be approved.

#### Fumigation Treatment and Compliance Agreements

We proposed to add a section to the regulations concerning fumigation treatment found in § 305.5 to provide that fumigation treatment facilities outside the United States enter into a compliance agreement, or an equivalent agreement such as a workplan agreement, with APHIS.

Upon further consideration, we have decided not to finalize this requirement at this time. The vast majority of fumigations performed outside the United States are done in connection with importation of regulated wood articles, such as Chinese wooden handicrafts, for which there are already compliance agreements or workplan agreements in place with the production facilities, or international agreements on treatment with certification through the International Plant Protection Convention. We will continue to closely monitor the issue and address any

problems that arise on a case-by-case basis. If circumstances dictate a need for greater APHIS oversight of these facilities, we will respond accordingly.

We also proposed, when fumigation of imported plants and plant products is conducted domestically, to require that importers enter into a compliance agreement with APHIS, and agree to comply with any requirements deemed necessary by the Administrator.

After further evaluation, we have determined that this proposed requirement is unnecessary. We proposed the requirement in order to establish consistency between requirements for the application of fumigation treatment of imported products, and the application of irradiation treatment for imported products.

In so doing, however, we failed to adequately consider an important distinction between the two types of treatment: Approved irradiation facilities are often not located in port environs, and are sometimes located hundreds of miles from ports of entry, fumigation is almost always conducted within port of entry environs, and, in the few instances when it is not, there are many long-standing mechanisms in place to ensure chain of custody and safeguarded transit to the fumigation facility. Accordingly, while requiring importers to enter into compliance agreements plays a vital role in ensuring adequate safeguarding of imported commodities during their transit from ports of entry to irradiation facilities, there is no corresponding need for compliance agreements for articles destined for fumigation.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 13771 and 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order (EO) 12866 and, therefore, has not been reviewed by the Office of Management and

Budget. This rule is not an EO 13771 regulatory action because this rule is not significant under EO 12866. Further, APHIS considers this rule to be a deregulatory action under EO 13771 as it will eliminate the need for specific rulemaking for the establishment of cold treatment facilities, thus reducing the time needed for approval of cold treatment facilities without affecting the analysis or mitigation of risk.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov website (see footnote 3 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

We are establishing general criteria for new cold treatment facilities in the Southern and Western United States. These general criteria will be supplemented as necessary by additional measures, as described in the facility's compliance agreement and based on its location and on the pests of concern associated with the regulated articles that will be treated at the facility. APHIS approval of new facilities will not require specific rulemaking. By eliminating the need for specific rulemaking for the establishment of cold treatment facilities, considerable time savings in bringing a new facility online may be achieved. A significant portion of the time needed to approve a new facility is due to the rulemaking process. This rule will reduce the time needed for approval of cold treatment facilities without affecting the analysis or mitigation of risk. The rule will simply set forth the general criteria, not approve any new facilities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

## Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

## Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

## Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection requirements included in this final rule, which were filed under 0579-0450, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

## E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

## List of Subjects in 7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

Accordingly, we are amending 7 CFR part 305 as follows:

### PART 305—PHYTOSANITARY TREATMENTS

1. The authority citation for part 305 continues to read as follows:

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. Section 305.1 is amended by adding in alphabetical order a definition for *treatment facility* to read as follows:

#### § 305.1 Definitions.

\* \* \* \* \*

*Treatment facility.* Any APHIS-certified place, warehouse, or approved enclosure where a treatment is conducted to mitigate a plant pest.

\* \* \* \* \*

3. Section 305.5 is amended as follows:

a. By redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c).

b. By adding an OMB citation at the end of the section.

The additions read as follows:

#### § 305.5 Chemical treatment requirements.

\* \* \* \* \*

(c) *Compliance agreements.* Any person who conducts a fumigation in the United States or operates a facility where fumigation is conducted in the United States for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) *Fumigation treatment facilities treating imported articles; compliance agreements with facility operators for fumigation in the United States.* If fumigation treatment of imported articles is conducted in the United States, the fumigation treatment facility operator or the person who conducts fumigation must sign a compliance agreement with APHIS. The fumigation facility operator or the person who conducts fumigation must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(2) *Fumigation treatment facilities treating articles moved interstate from Hawaii and U.S. territories.* Fumigation treatment facilities treating articles moved interstate from Hawaii and U.S. territories must complete a compliance agreement with APHIS as provided in § 318.13-3(d) of this chapter.

(3) *Fumigation treatment facilities treating articles moved interstate from areas quarantined for fruit flies.* Fumigation treatment facilities treating articles moved interstate from areas quarantined for fruit flies must complete a compliance agreement with APHIS as provided in § 301.32-6 of this chapter.

(4) *Fumigation treatment facilities treating articles moved interstate from areas quarantined for Asian citrus psyllid.* Fumigation treatment facilities treating articles moved interstate from areas quarantined only for Asian citrus psyllid, and not for citrus greening, must complete a compliance agreement with APHIS as provided in § 301.76-8 of this chapter.

\* \* \* \* \*

(Approved by the Office of Management and Budget under control number 0579-0450)

4. Section 305.6 is amended as follows:

- a. In paragraph (a) introductory text, by adding two sentences before the last sentence.
- b. By redesignating paragraph (a)(2) as paragraph (a)(3).
- c. By adding new paragraph (a)(2).
- d. By revising paragraphs (b) and (d)(15).
- e. In paragraph (e), by adding two sentences at the end of the paragraph.
- f. By revising paragraph (f).
- g. By removing paragraphs (g) and (h).
- h. By adding an OMB citation at the end of the section.

The additions and revisions read as follows:

§ 305.6 Cold treatment requirements.

(a) \* \* \* A facility will only be certified or recertified if the Administrator determines that the location of the facility is such that those Federal agencies involved in its operation and oversight have adequate resources to conduct the necessary operations at the facility, that the pest risks can be managed at that location, and that the facility meets all criteria for approval. Other agencies that have regulatory oversight and requirements must concur in writing with the establishment of the facility prior to APHIS approval. \* \* \*

\* \* \* \* \*

(2) Be capable of preventing the escape and spread of pests while regulated articles are at the facility; and

\* \* \* \* \*

(b)(1) *Location of facilities.* Where certified cold treatment facilities are available, an approved cold treatment may be conducted for any imported regulated article either prior to shipment to the United States or in the United States. For any regulated article moved interstate from Hawaii or U.S. territories, cold treatment may be conducted either prior to movement to the mainland United States or in the mainland United States. Cold treatment facilities may be located in any State on the mainland United States. For cold treatment facilities located in the area south of 39° latitude and west of 104° longitude, the following additional conditions must be met:

(i) Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from the port of entry or points of origin in the United States.

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

(iii) Untreated articles may not be removed from their packaging prior to treatment under any circumstances.



(iv) The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility is unable to properly treat a shipment.

(v) The facility may only treat articles approved by APHIS for treatment at the facility. Approved articles will be listed in the compliance agreement required in paragraph (f) of this section.

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

(vii) Regulated articles must be conveyed to the facility in a refrigerated (via motorized refrigeration equipment) conveyance at a temperature that minimizes the mobility of the pests of concern for the article.

(viii) The facility must apply all post-treatment safeguards required for certification under paragraph (a) of this section before releasing the articles.

(ix) The facility must remain locked when not in operation.

(x) The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. Proximity of host material to the facility will necessitate trapping or other pest monitoring activities, funded by the facility, to help prevent establishment of any escaped pests of concern, as approved by APHIS; these activities will be listed in the compliance agreement required in

paragraph (f) of this section. The treatment facility must have a pest management plan within the facility.

(xi) The facility must comply with any additional requirements including, but not limited to, the use of pest-proof packaging and container seals, that APHIS may require to prevent the escape of plant pests during transport to and from the cold treatment facility itself, for a particular facility based on local conditions, and for any other risk factors of concern. These activities will be listed in the compliance agreement required in paragraph (f) of this section.

(2) For articles that are moved interstate from areas quarantined for fruit flies, cold treatment facilities may be located either within or outside of the quarantined area. If the articles are treated outside the quarantined area, they must be accompanied to the facility by a limited permit issued in accordance with § 301.32-5(b) of this chapter and must be moved in accordance with any safeguards determined to be appropriate by APHIS.

\* \* \* \* \*

(d) \* \* \*

(15) An inspector will sample and cut fruit from each consignment after it has been cold treated to monitor treatment effectiveness. If a single live pest of concern in any stage of development is found, the consignment will be held until an investigation is completed and appropriate remedial actions have been implemented. If APHIS determines at any time that the safeguards contained in this section do not appear to be effective against the pests of concern, APHIS may suspend the importation of fruits from the originating country and conduct an investigation into the cause of the deficiency. APHIS may waive the sampling and cutting

requirement of paragraph (d)(15) of this section, provided that the national plant protection organization (NPPO) of the exporting country has conducted such sampling and cutting in the exporting country as part of a biometric sampling protocol approved by APHIS.

\* \* \* \* \*

(e) \* \* \* Facilities must be located within the local commuting area for APHIS employees for inspection purposes. Facilities treating imported articles must also be located within an area over which the U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force.

(f) *Compliance agreements.* Any person who operates a facility where cold treatment is conducted for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) *Compliance agreements with importers and facility operators for cold treatment in the United States.* If cold treatment of imported articles is conducted in the United States, both the importer and the operator of the cold treatment facility or the person who conducts the cold treatment must sign compliance agreements with APHIS. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival to the cold treatment facility in the United States. In the facility compliance agreement, the facility operator or person conducting the cold treatment must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(2) *Compliance agreements with cold treatment facilities outside the United States.* If cold treatment of imported articles is conducted outside the United States, the operator of the cold treatment facility must sign a compliance agreement or an equivalent agreement with APHIS and the NPPO of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and inform the Administrator of any noncompliance.

(3) *Cold treatment facilities treating articles moved interstate from Hawaii and U.S. territories.* Cold treatment facilities treating articles moved interstate from Hawaii and the U.S. territories must complete a compliance agreement with APHIS as provided in § 318.13-3(d) of this chapter.

(Approved by the Office of Management and Budget under control number 0579-0450)

5. Section 305.9 is amended by revising paragraphs (a)(1)(ii) and (vi) to read as follows:

§ 305.9 Irradiation treatment requirements.

\* \* \* \* \*

(a) \* \* \*

(1) \* \* \*

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on

pest risks, then State concurrence will not be required before APHIS approves the facility location.

\* \* \* \* \*

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

\* \* \* \* \*

Done in Washington, DC, this 6<sup>th</sup> day of February 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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